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K141179
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510(k) Summary

This summary of 510(k) safety and effective information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1. **Date Prepared**
   May 27, 2014

2. **Submitter's Information**
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3. **Device Information**

Proprietary Name:	A&D Medical UB-543Digital Blood Pressure Monitor
Common/Usual Name:	Blood Pressure Monitor
Classification name:	Non-invasive blood pressure measurement System 21 CFR 870-1130, Class II, 74DXN.

4. **Predicate Devices**
   A&D Model UB-511 & UB-512 Digital Blood Pressure Monitors with 510(k) number K042967. Predicate devices are designed and manufactured by the same company and facilities as the modified devices UB-543.

5. **Device Description – Technological and Operaional Characteristics**
   UB-543 uses an inflatable cuff which is wrapped around the patient's wrist. After the user pushes the "START" button, cuff is inflated automatically by an internal pump once the condition of the CPG (correct position guidance) algorithm is met. Measurement starts and the systolic and diastolic blood pressures are determined by oscillometric method. There is a quick exhaust mechanism so that the cuff pressure can be completely released urgently. There is a maximum pressure safety setting at 300mmHg. UB-543 will not inflate the cuff higher than 300mmHg. UB-543 will turn on an irregular heartbeat indicator if an irregular heartbeat was detected during the measurement process.

At the end of the measurement, the systolic and diastolic pressures with pulse rate are shown on the LCD and stored in the device memory. The cuff is also deflated automatically to 0 mmHg at the same time.

6. **Intended Use**

The A&D Medical UB-543 family digital blood pressure monitor is intended for used by adults with 12 years older to measure the systolic and diastolic blood pressure and pulse rate.

The intended user and the indication for use of A&D Medial UB-543 as described in the labeling are the same as their predicated devices, UB-511 & UB-512.

7. **Summary of Substantial Equivalence**

Modifications made from the predicate devices:

- Change the plastic molds so UB-543 has a different appearance
- Increase LCD display size
- Increase memory size
- Add time and date function
- Add correct position guideance (CPG) indicator

Product Specification Comparison

Parameter	**Predicate Devices (UB-511 & UB-512)**	**Modified Devices (UB-543)**
Power source	2 AAA size batteries	No change – the same
Battery Life	4 months with daily measurement	No change – the same
BP Measurement Method	Oscillometric Method	No change – the same
Measurement Range	BP : 20 to 280 mmHg Pulse : 40 to 200 pulse/min	BP : 0 to 299 mmHg Pulse : 40 to 200 pulse/min
Accuracy	BP : +/- 3mmHg or +/- 2% of measured value, whichever is greater Pulse : +/- 5 % (pulse)	BP : +/- 3mmHg Pulse : +/- 5 %
Pressurization Source	Automatic internal pump	No change – the same
Cuff Deflation Method	Quick exhaust valve	No change – the same
Display Type & Size	Liquid crystal display with 3.8 cm (1.5") x 2.3 cm (0.9")	Liquid crystal display with 6.0 cm (2.4") x 4.0 cm (1.6")
IHB (Irregular Heartbeats Detection)	More than +/-25% to the mean interval of all pulse intervals	No change – the same

Operating Environment	50^0F (10^0C) to 104^0F (40^0C) 15 %RH to 85% RH	No change – the same
Storage Environment	14^0F (-20^0C) to 140^0F (60^0C) 10 %RH to 95% RH	No change – the same
Pressure Indicator	USA JNC VII guideline	No change – the same
Data Memory Size with Time & Date	Last 30 measurements	Last 60 measurements each for user 1 and user 2
Pressure Sensor design	Static electricity capacity type	No change – the same
Number of user	UA-511 : one UB-512 : two	The same as UB-512

Dimensions in mm	58 (H) x 156 (W) x 145 (L)	88 (H) x 56 (W) x 18 (D)
Weight	82g without batteries	103g without batteries
Wrist Size	5.1 inches (13.0 cm) to 15.2 inches (38.6 cm)	No change – the same

Key Features Comparison

Parameter	**Predicate Devices (UB-511 & UB-512)**	**Modified Devices (UB-543)**
Field service	Not allowed	No Change – the same
Automatic zero at "START"	Yes	No Change – the same
Manual zero adjustment	Not allowed	No Change – the same
Calibration	Not allowed in the field	No Change – the same
Sterilization	Not needed	No Change – the same

Substantial Equivalence Conclusion:

UB-543 Digital blood pressure monitors have the following similarities to the predicate devices, UB-411 and UB-412 digital blood pressure monitors, which previously received the 510(k) clearance.

- Same Indication of Use
- Same intended use
- Same oscillometric method to determine the blood pressure & pulse rate
- Same inflation method – automatic internal pump
- Same deflation method – fast exhaust valve
- Same materials, no new materials used
- Same manufacturing processes at the same facility

As a conclusion, the intended use of the modified device, UB-543 as described in its labeling, has not changed as a result of the modifications. The fundamental scientific technology of the modified device, UB-543, has not changed, either. There is no significant difference that affects the safety or effectiveness of the modified device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-0002

June 27, 2014

A & D Co., Ltd.
c/o Dr. Jerry Wang
Director of Engineering
1756 Automation Parkway
San Jose, California 95131

Re: K141179
Trade/Device Name: A&D Medical UB-543 Digital Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Monitor
Regulatory Class: Class II (two)
Product Code: DXN
Dated: May 29, 2014
Received: May 30, 2014

Dear Dr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 OIR and Part 809; medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 OIR and Part 809, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K141179

Indications for Use

510(k) Number (if known):_____

Device Name: A&D Medical UB-543 Digital Blood Pressure Monitor

Indications For Use:

Measure blood pressure (systolic and diastolic) and pulse rate.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)